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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,725	01/27/2006	Hideki Tanji	10921.0296USWO	9962
52835	7590	10/24/2007		
HAMRE, SCHUMANN, MUELLER & LARSON, P.C. P.O. BOX 2902 MINNEAPOLIS, MN 55402-0902			EXAMINER TURK, NEIL N	
			ART UNIT 1797	PAPER NUMBER
			MAIL DATE 10/24/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/530,725

Applicant(s)

TANJI, HIDEKI

Examiner

Neil Turk

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 14-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Remarks**

This Office Action fully acknowledges Applicant's remarks filed on August 21<sup>st</sup>, 2007. Claims 1-18 are pending. Claims 14-28 have been withdrawn from consideration.

### ***Election/Restrictions***

Applicant's election of group I, claims 1-13, in the reply filed on November 27<sup>th</sup>, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Further, because of the reasons presented by Examiner in the Requirement for Restriction/Election dated November 7<sup>th</sup>, 2006, the restriction is made Final.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 1-13** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1-13 have been amended to recite that the response from the reference board "varies continuously with varying wavelength". Support for this recitation and the meaning of this recitation is not found in the specification. As such, this constitutes new matter in the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 1-13** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by the amended recitation, "...the response from the reference board varies continuously with varying wavelength..." The specification does not provide any description or disclosure to this recitation and such a recitation is thereby unclear and indefinite in the claims.

**Claims 7 and 10-12** are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: Claims 7 and 10-12 do not establish structural relationships between the elements so as to allow their respective functions. In claim 7, the storage is not given any structural relationship to the aforementioned elements, as well as the recited selector. Further, the controller as

recited in claim 10 is not given any structural relationship to the elements that precede it.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-13** are rejected under 35 U.S.C. 102(b) as being anticipated by Matzinger (5,780,304).

Matzinger discloses a method and apparatus for analyte detection having an on-strip standard. Matzinger discloses that the invention relates to a test device and method for optically measuring the concentration of glucose in whole blood (lines 8-12, col. 1). Matzinger discloses a test strip that has a reaction zone (with color-producing reagent), which varies in reflectance as a function of the quantity of analyte present, and a standard zone that is positioned so as to lead the reaction zone as the strip is inserted into a reading apparatus. Matzinger discloses that the apparatus has optical means for sequentially determining the reflectance value of the standard zone and for determining the reflectance value of the reaction zone after the strip has been inserted. The apparatus further includes means for calculating the presence and/or quantity of the analyte as a function of the standard zone and reaction zone reflectance (abstract; lines 26-60, col. 4; lines 61-67, col. 8; lines 1-31, col. 9). Matzinger discloses the apparatus

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12 is provided with a power switch 20 for activating the apparatus and the optics block 32 is affixed to the apparatus and operable to direct light through aperture 30 in rapid bursts, "chops", for a period of time each time it is activated (lines 50-67, col. 5; lines 19-35, col. 6, figs. 1-3). Matzinger discloses that the standard zone 60 provides a calibrated standard reflectance value against which the reflectance of the color-developed reaction zone may be measured so as to allow computation and reporting of the presence or quantity of the analyte (lines 40-67, col. 9; lines 1-21, col. 10; lines 6-28, col. 11; figs. 1, 4, and 6). Matzinger also discloses that the reflectance of the surface presented to the optics is measured at all the various positions and multiple readings are taken at each position in spaced periods of time (lines 30-67, col. 11, figs. 7-11). Matzinger further discloses that the apparatus views the gray target and read a value for its reflectance at each LED wavelength and compare the values to the factory stored values for the gray reading. If there is a difference between the stored readings and the actual readings an adjustment is made (lines 36-50, col. 6; lines 5-67, col. 13). Matzinger discloses further calibration measures and checks throughout column 14. Matzinger also discloses that the microprocessor employs a look-up table to provide proper coefficients for calibration of the specific test strip employed in the apparatus to correct K/S ratio (lines 1-60, col. 15). Examiner interprets the function of the microprocessor to check and compare the gray readings against factory-stored values for adjustments to correspond to the selector and calculation corrections as claimed.

***Response to Arguments***

Applicant's arguments filed August 21<sup>st</sup>, 2007 have been fully considered but they are not persuasive. The previous arguments of record made on 11/6/06 and 02/21/07 with regard to the restriction requirement are maintained, and claims 14-28 are withdrawn from consideration.

With regards to claims 6-13 rejected under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, as omitting essential structural relationships, Applicant addressed the structural relationships of claim 6, but did not address the likewise omitted structural relationships with respect to claim 7 (storage and selector) and claim 10 (controller) as previously discussed in the Action mailed on February 2<sup>nd</sup>, 2007.

With regards to claims 1-13 rejected under 35 U.S.C. 102(b) as anticipated by Matzinger (5,780,759), Applicant argues that Matzinger does not disclose or suggest a second detection step for irradiating light onto a reference board to detect a response from the reference board, where the response from the reference board varies continuously with varying wavelength. Examiner argues that Matzinger discloses calculating the presence and/or quantity of the analyte as a function of the standard zone and reaction zone reflectance (abstract; lines 26-60, col. 4, lines 40-67, col. 9; lines 1-21, col. 10; line 48, col. 11 – line 20, col. 12). Matzinger further discloses that in the calibration and operation of the device the apparatus is programmed to read the reflectance of the standard zone. Matzinger discloses calibrating the reflectance of the standard zone at readings first of with LED 660, than alternating between LED 940 and 660 (lines 53-67, col. 13, and col. 14, claim 2). Examiner asserts that the standard

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zone's response (reflectance) will vary continuously based on which LED (940, 660; varying wavelength) is applied to the standard zone. Examiner further asserts that such calibration and readings of the standard zone is used in conjunction with the reflectance reading of the reaction zone reflectance in order to provide calculation for a presence or quantity of the analyte in the liquid. Further, Applicant's arguments are drawn to new matter that has been added to the claims, as discussed above. As such, it is unclear what the amended portion of the claims means and the claims are indefinitely defined.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.




Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Turk whose telephone number is 571-272-8914. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT

  
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